

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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| Applicant's or agent's file reference BET04P0348 | FOR FURTHER ACTION | See item 4 below |
| International application No. PCT/IB2004/001409 | International filing date (<i>day/month/year</i>) 05 May 2004 (05.05.2004) | Priority date (<i>day/month/year</i>) 16 May 2003 (16.05.2003)] |
| International Patent Classification (IPC) or national classification and IPC ⁷ C07C 315/00, 315/06, 317/28 | | |
| Applicant ORGANISATION DE SYNTHÈSE MONDIALE ORSYMONDE | | |

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|-------------------------------------|---|---|-----------|---------------------|-------------------------------------|------------|----------|--------------------------|-------------|--|--------------------------|------------|----------------------------|-------------------------------------|-----------|---|--------------------------|------------|-------------------------|--------------------------|-------------|--|--------------------------|--------------|---|
| 1. | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a). | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. | This REPORT consists of a total of 7 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead. | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. | <p>This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> | <input checked="" type="checkbox"/> | Box No. I | Basis of the report | <input checked="" type="checkbox"/> | Box No. II | Priority | <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. II | Priority | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VI | Certain documents cited | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2). | | | | | | | | | | | | | | | | | | | | | | | | |

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|---|---|---|---|--------------------------------|
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35 | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Date of issuance of this report 18 November 2005 (18.11.2005)</td> </tr> <tr> <td style="padding: 2px;">Authorized officer Idhir Britel</td> </tr> <tr> <td style="padding: 2px;">Telephone No. +41 22 338 70 60</td> </tr> </table> | Date of issuance of this report 18 November 2005 (18.11.2005) | Authorized officer Idhir Britel | Telephone No. +41 22 338 70 60 |
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| Authorized officer Idhir Britel | | | | |
| Telephone No. +41 22 338 70 60 | | | | |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 05 JUL 2004

WIPO PCT

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IB2004/001409

International filing date (day/month/year) ✓
05.05.2004

Priority date (day/month/year)
16.05.2003

International Patent Classification (IPC) or both national classification and IPC
C07C315/00, C07C315/06, C07C317/28

Applicant
ORGANISATION DE SYNTHÈSE MONDIALE ORSYMONDE

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Lorenzo Varela, M.J.

Telephone No. +49 89 2399-8239



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/001409

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/B2004/001409

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, Inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|---------------------------------------|
| Novelty (N) | Yes: Claims | 5,8,9,12-14,16,17,22,23,26,27 |
| | No: Claims | 1-4,6,7,10,11,15,18,19-21,24,25,28-31 |
| Inventive step (IS) | Yes: Claims | . |
| | No: Claims | 5,8,9,12-14,16,17,22,23,26,27 |
| Industrial applicability (IA) | Yes: Claims | 1-31 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

- D1: US-A-4 927 855 (LAFON LOUIS) 22 May 1990 (1990-05-22)
D2: WO 02 10125 A (GERSHON NEOMI ;SINGER CLAUDE (IL); TEVA PHARMA (IL); ARONHIME JUDI) 7 February 2002 (2002-02-07)
D3: US-A-5 618 845 (STONG DAVID ET AL) 8 April 1997 (1997-04-08)

1. The present application relates to a process for preparing modafinil from diphenylmethysulphinyl acetate and ammonia at a certain temperature and stirring speed in order to obtain a certain granulometry.

Novelty

2. The subject-matter of claims 1-4, 6, 7, 10, 11, 15, 18, 19-21, 24, 25 and 28-31 is not novel in the sense of Art.33(2) PCT. D1 and D2 disclose a process for preparing modafinil from diphenylmethysulphinyl acetate and ammonia (see the passages mentioned in the search report). Taking into account that the process is as well carried out at a certain temperature and at a certain stirring speed, a certain granulometry is obtained as well and furthermore, as the temperature, solvent and time of reaction follow under the scope of those ones in the application, the granulometric median will be as well as in the application. With respect to claim 31 the applicant's attention is drawn to the fact that known compounds are not novel even if they are produced by a new method (which furthermore is not the case in the present application). Hence, the subject-matter of claims 1-4, 6, 7, 10, 11, 15, 18, 19-21, 24, 25 and 28-31 is not novel.

Inventive step

3. Dependent claims 5, 8, 9, 12-14, 16, 17, 22, 23, 26 and 27 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to inventive step. The use of a different concentration of DMSAM/NH₃ or reaction time can only be considered as inventive if comparative examples are provided showing that these technical features lead to a) a granulometric mean which is specially useful with respect to the granulometric mean obtained in the state of the art or b) to any other unexpected

effect. Furthermore, the production of different polymorphic forms of modafinil depending on the reaction/recrystallization conditions is known in the state of the art (D3).

Further matters

4. It is clear from the description on pages 5, 7, 8 and the examples that the reaction temperature, stirring speed, concentration of the DMSAM and solvent are essential to the definition of the invention. Since independent claim 1 does not contain these features, it does not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3 (b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.
5. Claims 1, 10, 13 and 15 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not defined. The claims attempt to define the subject-matter in terms of the result to be achieved. Such a definition is only allowable under the conditions elaborated in the Guidelines C-III, 4.7.-In this instance, however, such a formulation is not allowable because it appears possible to define the subject-matter in more concrete terms, viz. in terms of how the effect is to be achieved.
6. The application does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (contrary to Art. 5 PCT. Polymorphic forms I and III are mentioned in the application and in the claims but no physical/chemical data in order to clearly identify these polymorphic forms are provided. Hence, the skilled person in the art would not be able to identify such polymorphic forms.
7. The terms "substantially" and "notably" used on page 8 are vague and imprecise, rendering therefore unclear the scope of the protection sought, contrary to Art. 6 PCT.
8. The expressions "complete dissolution" and "complete crystallization" used in the claims should be replaced by the definition of those expressions on page 10 and 11 in the description.
9. Features introduced by terms like "preferably" in claim 7 have no limiting effect on the

scope of the claim including them (see PCT Guidelines, C-III, 4.6). The presence of such non-limiting features is however detrimental to the conciseness of said claim, contrary to Art. 6 PCT.

10. When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims.
11. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 19 (2) and 34 (2) b) PCT, the applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based.

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.